DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d1638

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53273

December 13, 1996

Marcelino R. Amaral, Jr.
Marcelino Amaral and Sons Dairy
20207 4th Avenue
Stevinson, California 95374

WARNING LETTER

Dear Mr. Amaral:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 24, 25 and 28, 1996, by Food and Drug Administration (FDA) Investigator Christopher J. Lee have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On August 26, 1996, you consigned a dairy cow (identified by USDA laboratory report number 367714) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the muscle at 9.00 parts per million (ppm) and in the liver at 4.20 ppm. The tolerance level for sulfadimethoxine in the edible tissues of cattle is 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are

ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate record keeping system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

You are adulterating the drug Albon brand sulfadimethoxine within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with its approved labeling. Sulfadimethoxine labeling warns against releasing dairy cattle for slaughter for food within five days after the last treatment. Not adhering to the withdrawal time for this drug is likely the cause of the illegal residues found in the animal you sold for slaughter. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

You are using the drug Pen-Aqueous brand penicillin G procaine in a manner not in conformance with its approved labeling. Labeling for penicillin G proacaine specifies it is to be administered by intramuscular injection. Your practice of mixing of 10 mls of penicillin G procaine with 10 mls of distilled water to create an intrauterine infusion for use in your dairy cows is an unapproved use for which safety and efficacy have not been established. Creating the infusion constitutes manufacturing a new animal drug which requires the submission of a New Animal Drug Application for for FDA approval.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The

fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]